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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/693,317	10/23/2003	Per Johan Lundberg	1103326-0203	8231

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PATENT DEPARTMENT
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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	**PAPER NUMBER**
1615	

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11/16/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/693,317	LUNDBERG ET AL.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17,19 and 21-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19 and 21-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *08/17/07; 10/23/03; 12/07/04*
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action and Applicant's Arguments filed 04/27/06 and the Information Disclosure Statement (IDS) filed 08/17/07 is acknowledged.

Upon further review and consideration, the previous Non-Final Office Action filed 11/02/05 has been withdrawn. The following are the new grounds of rejection:

Claims 1-17, 19 and 21-24 are pending in this action. Claims 1-17 and 19 have been amended. New claims 21-24 have been added. Claims 18 and 20 have been cancelled. Claims 1-17, 19 and 21-24 are rejected.

Claim Objections

Claim 5 is objected to because of the following informalities:

Claim 5 recites dependency upon claim 3. It appears that claim 5 should instead recite dependency upon claim 4, to provide for proper antecedent basis for the amino acid. Appropriate correction is required.

Claim 19 is objected to because of the following informalities:

Claim 19, last line recites "any of claims 1-16...". The claim should be amended to recite "any *one* of claims 1-16...".

* * * * *

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-17, 19 and 21-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are indefinite because it is unclear as to what is being claimed. The claims are unclear in terms of whether distinct layers are provided in the dosage form that result from the reaction of the distinct layers or whether there are separate layers that can be reactive in the dosage form. The claims are vague in terms of how the distinct layers are obtained. It does not seem reasonable to assume that when the layers are coated, they react, because a product is being claimed.

Clarification is requested.

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 recites the limitation "wherein the alkaline *organic* compound" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

* * * * *

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 17 is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,013,281 (the '281 Patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 1 of the '281 Patent also claims a process for preparing an oral pharmaceutical formulation that comprises the steps of forming a core material comprising a proton pump inhibitor and at least one alkaline reacting compound, wherein the alkaline reacting compound is about 0.1 mmol/g dry ingredients in the alkaline part of the core material, and applying an enteric coating polymer layer so as to surround the core material thereby forming in situ a separating layer as a water soluble salt product between the alkaline compound and the enteric coating polymer.

Claim 1 of the '281 Patent differs from instant claim 17 in that instant claim 17 recites "optionally pharmaceutically acceptable excipients", whereas claim 1 of '281 does not recite the

optional use of excipients. Claim 1 of '281 also differs from instant claim 17 in terms of the recitation of the concentration of the alkaline reacting compound (about 0.1 mmol/g dry ingredients) whereas claim instant claim 17 does not recite any concentration of the alkaline reacting compound. However, note that instant claim 6 recites a concentration of the alkaline reacting compound, provided in a concentration of more than 0.1 mmol/g dry ingredients.

The Examiner points out that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would be *prima facie* obvious to one of ordinary skill in the art to optimize amounts/ranges through the use of routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art.

* * * * *

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-3, 7, 8, 10, 11, 14-17, 19, 21 and 23 are rejected under 35 U.S.C. 102(b) as being anticipated by Lovgren *et al.* (U.S. Pat. No. 4,786,505).

Lovgren *et al.* ('505) disclose a pharmaceutical preparation, process for preparing thereof and use for the treatment of gastrointestinal diseases, whereby the preparation contains omeprazole together with an alkaline reacting compound or an alkaline salt of omeprazole optionally together with an alkaline compound as the core material, one or more subcoating layers comprising inert reacting compounds, which are water soluble or rapidly disintegrating in water, or polymeric, water-soluble film-forming compounds, optionally containing pH-buffering alkaline compounds and an enteric coating (see Abstract); (col. 3, lines 15-33).

The omeprazole core is mixed with inert, preferably water-soluble constituents and with an alkaline reacting substance. Suitable substances disclosed include aluminum salts of phosphoric acid, carbonic acid, calcium and magnesium hydroxides and the like (col. 3, lines 35065).

The powder mixture is then formulated into small beads, such as pellets, tablets and gelatin (hard or soft) capsules (col. 3, lines 66-68).

The omeprazole containing alkaline reacting cores must be separated from the enteric coating polymer(s) containing free carboxyl groups. Substances for the separating layer include magnesium oxide, hydroxide or carbonate, carbonate or silicate and the like (col. 4, lines 3-45).

The enteric coating layer is applied onto the subcoated cores by conventional coating techniques. Suitable enteric coating polymers disclosed include hydroxypropylmethylcellulose phthalate and co-polymerized methacrylic acid/methacrylic acid methyl esters (col. 4, line 60 – col. 5, line 18).

The final dosage form is either an enteric coated tablet or capsule or in the case of enteric coated pellets, pellets dispensed in hard gelatin capsules or sachets or pellets formulated into tablets (col. 5, line 60 – col. 6, line 5).

Processes for manufacturing the dosage form are disclosed at col. 6 and in the Examples.

The instant claims are anticipated by Lovgren et al.

* * * * *

Claims 1-3, 7, 8, 10, 11, 14-17, 19, 21, 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Bengtsson *et al.* (WO 95/01783).

Bengtsson *et al.* ('783) disclose a pharmaceutical formulation comprising omeprazole, method for manufacture and use of such formulation, whereby the formulation contains a core material in the form of pellets, granules or tablets comprising a magnesium salt of omeprazole, optionally together with an alkaline reacting compound, and on said core material, one or more subcoating layers optionally comprising tablet excipients, which are soluble or insoluble but disintegrating in water, or polymeric, film-forming compounds, optionally containing pH-buffering, alkaline compounds between the core and outer layer, which is an enteric coating. These layer(s) separate the core material from the outer layer enteric coating (see Abstract); (p. 3, line 15 – p. 4, line 12).

Alkaline reacting compounds disclosed include magnesium and aluminum salts of phosphoric acid, carbonic acid, and other suitable weak inorganic or organic acids (p. 6, line 29 – p. 7, line 11).

Materials for the separating or subcoating layer are disclosed at p. 7, line 19 – p. 8, line 25.

The enteric coating polymer layer can comprise substances such as methacrylic acid/methacrylic acid methyl ester copolymer and hydroxypropylmethylcellulose acetate succinate (p. 9, lines 1-23).

The instant claims are anticipated by Bengtsson et al.

* * * * *

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17, 19 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lovgren *et al.* (U.S. Pat. No. 4,786,505) in view of Uda (U.S. Pat. No. 5,635,520).

Lovgren *et al.* ('505), as discussed above, teach a pharmaceutical preparation, process for preparing thereof and use for the treatment of gastrointestinal diseases, whereby the preparation contains omeprazole together with an alkaline reacting compound or an alkaline salt of omeprazole optionally together with an alkaline compound as the core material, one or more subcoating layers comprising inert reacting compounds, which are water soluble or rapidly disintegrating in water, or polymeric, water-soluble film-forming compounds, optionally containing pH-buffering alkaline compounds and an enteric coating (see Abstract); (col. 3, lines 15-33).

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The final dosage form is either an enteric coated tablet or capsule or in the case of enteric coated pellets, pellets dispensed in hard gelatin capsules or sachets or pellets formulated into tablets (col. 5, line 60 – col. 6, line 5).

Processes for manufacturing the dosage form are disclosed at col. 6 and in the Examples.

With regards to the amounts of alkaline reacting compound, it is noted that generally, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). It would be *prima facie* obvious to one of ordinary skill in the art to optimize amounts/ranges through the use of routine or manipulative experimentation to obtain optimal results, as these are variable parameters attainable within the art.

Lovgren *et al.* teach omeprazole. They do not teach lansoprazole and pantoprazole, nor the alkaline reacting compound to be an amino acid (i.e., arginine).

Uda ('520) teaches a composition comprising a benzimidazole compound having antiulcer activity, for the treatment of gastrointestinal ulcers (see Abstract). Suitable benzimidazole compounds disclosed include lansoprazole, pantoprazole and omeprazole (col. 8, lines 10-33). The compound can be used in the form of a physiologically acceptable salt. The

salt includes inorganic bases, salts with organic bases and salts with basic amino acids (col. 8, lines 39-43). The basic amino acids may be arginine, lysine and so on (col. 8, lines 43-50).

It would have been obvious to one of ordinary skill in the art to incorporate the basic amino acids disclosed with antiulcer drugs such as lansoprazole, pantoprazole or omeprazole as taught by Uda within the formulations of Lovgren. One would do so with a reasonable expectation of success because Uda teaches lansoprazole, pantoprazole or omeprazole to be effective active ingredients for use in their formulaion and teach that the salts with basic amino acids (lysine, arginine) are also included to provide for an antiulcer composition effective for the treatment of gastrointestinal disorders and conditions.

* * * * *

Claims 1-17, 19 and 21-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bengtsson *et al.* (WO 95/01783) in view of Uda (U.S. Pat. No. 5,635,520).

Bengtsson *et al.* ('783), as discussed above, teach a pharmaceutical formulation comprising omeprazole, method for manufacture and use of such formulation, whereby the formulation contains a core material in the form of pellets, granules or tablets comprising a magnesium salt of omeprazole, optionally together with an alkaline reacting compound, and on said core material, one or more subcoating layers optionally comprising tablet excipients, which are soluble or insoluble but disintegrating in water, or polymeric, film-forming compounds, optionally containing pH-buffering, alkaline compounds between the core and outer layer, which is an enteric coating. These layer(s) separate the core material from the outer layer enteric coating (see Abstract); (p. 3, line 15 – p. 4, line 12).

Alkaline reacting compounds disclosed include magnesium and aluminum salts of phosphoric acid, carbonic acid, and other suitable weak inorganic or organic acids (p. 6, line 29 – p. 7, line 11).

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It would have been obvious to one of ordinary skill in the art to incorporate the basic amino acids disclosed with antiulcer drugs such as lansoprazole, pantoprazole or omeprazole as taught by Uda within the formulations of Bengtsson. One would do so with a reasonable expectation of success because Uda teaches lansoprazole, pantoprazole or omeprazole to be effective active ingredients for use in their formulaion and teach that the salts with basic amino

acids (lysine, arginine) are also included to provide for an antiulcer composition effective for the treatment of gastrointestinal disorders and conditions.

Conclusion

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours. (Wednesdays - Telework).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit 1615

November 13, 2007

HUMERA N SHEIKH
PRIMARY EXAMINER